(d) and (e) Yes, following steps are being taken to tighten the regulation of clinical trials in the country:—

(1) From 15th June, 2009, it has been made mandatory to register all clinical trials permitted on or after the said date at Indian Council of Medical Research (ICMR) registry at ***www.ctri.in*** before enrolling first patient in the study. Such registration will improve transparency and accountability of all stake holders involved in clinical trials.

(2) The Drugs and Cosmetics (Amendment) Bill 2007 introduced in Rajya Sabha on 21.08.2007 contains separate regulatory provisions for clinical trial.

(3) For registration of Clinical Research Organization (CRO) draft guidelines have been prepared and posted on CDSCO website for public/comments.

Loopholes in medicine regulatory system

2334. SHRIMATI SHOBHANA BHARTIA:
SHRI N.K. SINGH:
DR. JANARDHAN WAGHMARE:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the National Pharmaceutical Pricing Authority (NPPA) has urged his Ministry to plug loopholes in the regulatory system that allow companies to raise medicine prices by adding ingredients not listed under the law relating to drugs and cosmetics;

(b) if so, the details thereof and the reaction of Government thereto;

(c) whether his Ministry in consultation with the drug regulator propose to take any further action in this regard; and

(d) if so, the details thereof?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (d) Yes. The National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals has brought the matter to the notice of the Ministry of Health and Family Welfare that companies are resorting to the tactics of mixing food and nutrition supplements with certain drug formulations so as to circumvent the price control mechanism. The NPPA has suggested some corrective measures to be implemented in consultation with the Drugs Consultative Committee and the Central Committee on Food Standards, which, if needed, could be appropriately incorporated in the provisions of the Drugs and Cosmetics Rules, 1945 and the Prevention of Food Adulteration Rules, 1955.

Setting up of Health Council

2335. MS. MABEL REBELLO: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state: